K002007

JAN 2 5 2001

SULZER *MEDICA*

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

Phone (512) 435-3200
FAX (512) 435-3350
WATS (800) 648-1579 (US and Canada)

510(k) SUMMARY

per 21 CFR §807.92

Submitter	*Contact*
Sulzer Carbomedics Inc. 1300 East Anderson Lane Austin, Texas 78752-1793	Lisa O'Connor Regulatory Affairs Associate Phone: 512-435-3523 Fax: 512-435-3350 Email: loconnor@carbomedics.com

Date of Summary: June 30, 2000
Common Name: Vascular Graft
Proprietary Name: Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis

Description of Device: The Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis is an externally reinforced, gelatin-sealed, warp knitted polyester graft. The knitted polyester material has been impregnated with an absorbable mammalian gelatin that seals the prosthesis in the same manner as the fibrin deposited in traditional preclotting procedures. The gelatin sealant obviates the need for preclotting prior to implantation. The gelatin is of USP standard and is derived from bovine bone sourced exclusively in the United States. The result is a vascular prosthesis that does not require preclotting even when patients have been anticoagulated or when bleeding is a prime concern. The gelatin has been shown to be safe and effective through the approval of PMA P890045 for the Sulzer Vascutek Gelseal™ Vascular Prosthesis on January 11, 1993 and PMA P890045/S001 for the Sulzer Vascutek Gelsoft™ Vascular Prosthesis on July 5, 1995.

Statement of Intended Use: The Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis is intended for extra-anatomical vascular repair, primarily for axillo-femoral/bifemoral bypass and femoro-popliteal reconstruction.

Technological Comparison: For purposes of this submission, the Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis was compared to the following predicate devices:

- Sulzer Vascutek® Gelsoft™ Vascular Prosthesis: P890045/S001, and K990503
- Sulzer Vascutek® Externally Reinforced Triaxial™ Vascular Prosthesis: K853101/A, K910864

Testing: Side-by-side *in vitro* testing which evaluated Burst Strength, Kink Radius, Tensile Strength, Suture Retention, Nominal Wall Thickness, Flat Stock Wall Thickness, and External Support Peel Strength was performed using the Sulzer Vascutek Gelsoft™ ERS and the Sulzer Vascutek Externally Reinforced Triaxial™ Graft. The testing demonstrated that the gelatin-sealed and non-gelatin sealed externally reinforced grafts intended for systemic vascular repair have similar base fabric porosities and *in vitro* strength characteristics. In addition, clinical patency tests have shown that the device is safe and effective for clinical use.

Appropriate testing demonstrated that the Gelsoft™ ERS is substantially equivalent to the predicate devices for its intended use.

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Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Manager for Sulzer Carbomedics Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Edward E. Newton
Regulatory Affairs Manager
Sulzer Carbomedics Inc.
June 30, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2001

Ms. Lisa Peterson
Regulatory Affairs Associate
Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K002007/S1
Trade Name: Sulzer Vascutek Gelsoft™ ERS Vascular Prosthesis (non-rifampin-bonded) for Extra-Anatomical Use
Regulatory Class: II (two)
Product Code: DSY
Dated: December 15, 2000
Received: December 18, 2000

Dear Ms. Peterson:

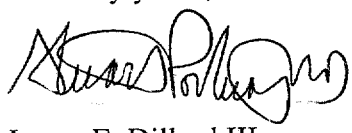
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
~~Director~~
Division of Cardiovascular and
~~Respir~~atory Devices
Office of Device Evaluation
~~Center for~~ Devices and
Radiological Health

Indications For Use

510(K) Number: Unknown

Device Name: Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis

Indications for Use: The Sulzer Vascutek® Gelsoft™ ERS Vascular Prosthesis is indicated for extra-anatomical vascular repair, primarily for axillo-femoral/bifemoral bypass and femoro-popliteal reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

1-24-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K002007